

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

**IBEW LOCAL 716 ELECTRICAL
MEDICAL TRUST,**

Plaintiff,

v.

**MCKESSON CORPORATION;
CARDINAL HEALTH, INC.;
AMERISOURCEBERGEN CORPORATION;
H.D. SMITH, LLC f/k/a
H.D. SMITH WHOLESALE DRUG CO.;
HENRY SCHEIN, INC.;
ANDA, INC.;
MORRIS & DICKSON CO., LLC;
TEVA PHARMACEUTICAL
INDUSTRIES, LTD.;
TEVA PHARMACEUTICALS USA, INC.;
CEPHALON, INC.;
JOHNSON & JOHNSON;
JANSSEN PHARMACEUTICALS, INC.;
ORTHO-MCNEIL-JANSSEN
PHARMACEUTICALS, INC. n/k/a
JANSSEN PHARMACEUTICALS, INC.;
JANSSEN PHARMACEUTICA INC. n/k/a
JANSSEN PHARMACEUTICALS, INC.;
ENDO HEALTH SOLUTIONS INC.;
ENDO PHARMACEUTICALS, INC.;
ALLERGAN PLC f/k/a ACTAVIS PLC;
ALLERGAN FINANCE, LLC;
ALLERGAN SALES, LLC;
ALLERGAN USA, INC.;
WATSON PHARMACEUTICALS, INC.
n/k/a ACTAVIS, INC.;
WATSON LABORATORIES, INC.;
ACTAVIS LLC;
ACTAVIS PHARMA, INC. f/k/a
WATSON PHARMA, INC.;
MALLINCKRODT, PLC d/b/a**

Case No. _____

COMPLAINT

JURY TRIAL DEMANDED

MALLINCKRODT PHARMACEUTICALS;)
MALLINCKRODT, LLC;)
AMNEAL PHARMACEUTICALS, LLC;)
AMNEAL PHARMACEUTICALS, INC.;)
ASSERTIO THERAPEUTICS, INC.;)
ABBOTT LABORATORIES;)
ABBOTT LABORATORIES, INC.;)
NORAMCO, INC.;)
PAR PHARMACEUTICAL, INC.;)
PAR PHARMACEUTICALS COMPANIES,)
INC.;)
CVS HEALTH CORPORATION;)
CVS PHARMACY, INC.;)
WALMART INC.;)
WALMART STORES EAST, LP;)
WALGREEN EASTERN CO., INC.;)
WALGREENS BOOTS ALLIANCE INC.;)
KROGER CO.;)
KROGER LIMITED PARTNERSHIP II)
RITE AID CORPORATION;)
and DOE 1-100, being those)
persons, firms, corporations, agents,)
servants and/or employees who authorized,)
ordered and/or committed the acts described)
in this Complaint and whose names when)
ascertained will be substituted by)
amendment by Plaintiff,)
)
Defendants.)

The Plaintiff, IBEW LOCAL 716 ELECTRICAL MEDICAL TRUST, a health and welfare benefit fund, (hereinafter referred to as LOCAL 716), files this Complaint against the Defendants as follows:

INTRODUCTION

1. The opioid epidemic plaguing LOCAL 716 has been directly and proximately caused by Defendants' false, deceptive, and fraudulent marketing of prescription opioids, and Defendants' conscious and/or negligent oversupply and diversion of prescription opioids. The addiction epidemic of prescription opioid abuse in the United States has caused health and

welfare benefit funds, including LOCAL 716, extraordinary economic damages. This opioid epidemic has financially damaged LOCAL 716. LOCAL 716 seeks, in part, reimbursement of payments made by opioid-related costs of medical care, including monies paid for the over-prescription of opioid pills, opioid-related illnesses, and other costs.

2. Prescription opioids are deadlier than heroin, with related drug overdose deaths surpassing car accident deaths in the United States. The direct costs incurred by health and welfare funds, including LOCAL 716, are overwhelming.

3. This epidemic and its consequences could have been, and should have been, prevented by the Defendants who control the U.S. drug distribution industry and the Defendants who manufacture prescription opioids. These Defendants have profited greatly by allowing the geographic area that LOCAL 716 serves to become flooded with prescription opioids.

4. The drug distribution industry is supposed to serve as a "check" in the drug delivery system by securing and monitoring opioids at every step of the stream of commerce, protecting them from theft and misuse, and refusing to fulfill suspicious or unusual orders by downstream pharmacies, doctors, clinics, or patients. Defendants woefully failed in this duty by consciously ignoring known or knowable problems and data in their custody, control, and/or possession.

5. Defendants thus intentionally and negligently created conditions in which vast amounts of opioids have overflowed freely from and through the Defendants to innocent patients who became addicted, to opioid abusers, and even to illicit drug dealers - with distributors regularly fulfilling suspicious orders from pharmacies and clinics, who were economically incentivized to ignore "red flags" at the point of sale and before dispensing the pills.

6. Defendants' wrongful conduct has allowed millions of opioid pills to be diverted

from legitimate channels of distribution into the illicit black market in quantities that have fueled the opioid epidemic in the LOCAL 716 area – where the participants of LOCAL 716 and their families live and work. This is "opioid diversion." Acting against their common law and statutory duties, Defendants have caused a black market in opioid pills and other opioid drugs in which opioid diversion is rampant. As a result, unknowing patients and unauthorized opioid users have ready access to illicit sources of diverted opioids.

7. For years, Defendants and their agents have had the ability to substantially reduce the death toll and adverse economic consequences of opioid diversion, including the deaths and health ruination of hundreds of thousands of citizens. Substantial expenditures by LOCAL 716 in dealing with the problem have gone un-recouped and unreimbursed. All the Defendants share responsibility for perpetuating the epidemic.

8. Defendants have foreseeably caused damages to LOCAL 716, including the unreimbursed and/or un-recouped costs from the over-prescription of opioids.

9. LOCAL 716 brings this civil action for injunctive relief, compensatory damages, statutory damages, and any other relief allowed by law against the Defendant opioid drug distributors, retailers, and manufacturers that, by their actions and omissions, knowingly or negligently have distributed, dispensed, and/or over-prescribed prescription opioid drugs in a manner that foreseeably injured, and continues to injure, LOCAL 716.

PARTIES

A. Plaintiff

10. The Plaintiff LOCAL 716 is a health and welfare benefit fund. The participants in the LOCAL 716 Fund are primarily located in Houston, Texas. At all relevant times, Plaintiff has paid and/or provided reimbursement for some or the entire purchase price on behalf of its

participants for prescription opioids which are manufactured, marketed, promoted, sold, and/or distributed by the Defendants in Texas. LOCAL 716 has these paid prescription costs and other health care costs for its participants in Texas. Plaintiff has sustained injury as a result of Defendants' illegal and wrongful conduct alleged herein, including but not limited to, incurring unreimbursed costs related to the over-prescription of opioids and opioid-related health care provided to participants.

B. Defendants

i. Distributor Defendants

11. McKesson Corporation ("McKesson") has its principal place of business in San Francisco, California, and is incorporated under the laws of Delaware. During all relevant times, McKesson has distributed substantial amounts of prescription opioids to providers and retailers in the geographic area served by LOCAL 716.

12. Cardinal Health, Inc. ("Cardinal") has its principal place of business in Ohio and is incorporated under the laws of Ohio. During all relevant times, Cardinal has distributed substantial amounts of prescription opioids to providers and retailers in the geographic area of participants of LOCAL 716.

13. AmerisourceBergen Corporation has its principal place of business in Pennsylvania and is incorporated under the laws of Delaware. During all relevant times, AmerisourceBergen has distributed substantial amounts of prescription opioids to providers and retailers in the geographic area of the participants of LOCAL 716.

14. Defendant Anda, Inc., ("Anda") through its various DEA registrant subsidiaries and affiliated entities, including but not limited to Anda Pharmaceuticals, Inc., is the fourth largest distributor of generic pharmaceuticals in the United States. Anda is a Florida corporation with its

principal place of business in Weston, Florida. In October 2016, Defendant Teva Ltd. Acquired Anda from Defendant Allergan plc (i.e., Defendant Actavis), for \$500 million in cash. During all relevant times, Anda has distributed substantial amounts of prescription opioids to providers and retailers in the geographic area of the participants of LOCAL 716.

15. Defendant H.D. Smith, LLC f/k/a H.D. Smith Wholesale Drug Co. (“H.D. Smith”) through its various DEA registered subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distribute opioids throughout the United States, including Texas and the geographic area of the participants of LOCAL 716. H.D. Smith is a privately held independent pharmaceuticals distributor of the wholesale brand, generic and specialty pharmaceuticals, and is a Delaware corporation with its principal place of business in Illinois. H.D. Smith Wholesale Drug Co. has been restructured and is currently doing business as H.D. Smith, LLC. H.D. Smith, LLC’s sole member is H.D. Smith Holdings, LLC, and its sole member is H.D. Smith Holding Company, a Delaware corporation with its principal place of business in Illinois. H.D. Smith is the largest independent wholesaler in the United States. In January 2018, Defendant AmerisourceBergen acquired H.D. Smith. During all relevant times, H.D. Smith has distributed substantial amounts of prescription opioids to providers and retailers in the geographic area of the participants of LOCAL 716.

16. Defendant Henry Schein, Inc. (Henry Schein) describes its business as providing products and services to integrated health systems, designed specifically for and focused exclusively on the non-acute care space. Henry Schein is incorporated in Delaware, with its principal place of business located in Melville, New York.

17. Henry Schein distributes, among other things, branded and generic pharmaceuticals to customers that include dental practitioners, dental laboratories, animal health

practices and clinics, and office-based medical practitioners, ambulatory surgery centers, and other institutions.

18. At all relevant times, Henry Schein was in the business of distributing and redistributing, pharmaceutical products to consumers within Texas and the geographic area of the participants of LOCAL 716.

19. In 2015, Henry Schein reported that its sales reached a record of \$10.4 billion and that it had grown at a compound annual rate of approximately 16 percent since becoming a public company in 1995. Overall, it is the world's largest provider of health care products and services to office-based dental, animal health, and medical practitioners.

20. Morris and Dickson Co., LLC ("Morris and Dickson") is a Louisiana limited liability company and maintains its principal place of business in Shreveport, Louisiana. During all relevant times, Morris and Dickson have distributed substantial amounts of prescription opioids to providers and retailers in the geographic area of the participants of LOCAL 716.

21. McKesson, Cardinal, AmerisourceBergen, H.D. Smith, Henry Schein, Anda, and Morris and Dickson are collectively referred to hereinafter as "Distributor Defendants."

ii. Manufacturer Defendants

22. Cephalon, Inc. ("Cephalon") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Cephalon manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the U.S. and Texas, including the geographic area served by LOCAL 716. The FDA has approved Actiq and Fentora only for the "management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain." In 2008, Cephalon pled guilty to a criminal

violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay \$425 million.

23. Teva Pharmaceutical Industries, Ltd. (“Teva Ltd.”) is an Israeli corporation with its principal place of business in Petah Tikva, Israel. Teva Pharmaceuticals USA, Inc. (“Teva USA”) is a wholly-owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in Pennsylvania. Teva USA acquired Cephalon in October 2011.

24. Teva Ltd., Teva USA, and Cephalon collaborate to market and sell Cephalon products in the U.S. Teva Ltd. conducts all sales and marketing activities for Cephalon in the U.S. through Teva USA. Teva Ltd. and Teva USA publicize Actiq and Fentora as Teva products. Teva USA sells all former Cephalon branded products through its “specialty medicines” division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids marketed and sold in Texas, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva Ltd. has directed Cephalon to disclose that it is a wholly-owned subsidiary of Teva Ltd. on prescription savings cards distributed in Texas, indicating Teva Ltd. would be responsible for covering certain co-pay costs. All of Cephalon’s promotional websites, including those for Actiq and Fentora, prominently display Teva Ltd.’s logo. Teva Ltd.’s financial reports list Cephalon’s and Teva USA’s sales as its own. Through interrelated operations like these, Teva Ltd. operates in Texas and the rest of the U.S. through its subsidiaries Cephalon and Teva USA. The U.S. is the largest of Teva Ltd.’s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies’ business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva

USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. (Teva Ltd., Teva USA, and Cephalon, Inc. are hereinafter collectively referred to as “Cephalon.”)

25. Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly-owned subsidiary of Johnson & Johnson (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

26. Ortho-McNeil-Janssen Pharmaceuticals, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Janssen Pharmaceutica Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

27. Defendant Noramco, Inc. is a Delaware company headquartered in Wilmington, Delaware, and was a wholly-owned subsidiary of J&J until July 2016. Noramco, Inc. is or had been part of J&J's opioid processing. It makes active pharmaceutical ingredients ("APIs") for opioid painkillers.

28. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., Noramco, Inc., and J&J hereinafter are collectively referred to as “Janssen.”). Janssen manufactures, promotes, sells, and distributes drugs in the U.S., including Texas, including the opioid Duragesic. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER.

29. Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals Inc. is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

30. Defendant Par Pharmaceutical, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. is a wholly-owned subsidiary of Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc.

31. Defendant Par Pharmaceuticals Companies, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York (Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. collectively, "Par Pharmaceutical"). Par Pharmaceutical was acquired by Endo International plc in September 2015 and is an operating company of Endo International plc. (Endo Health Solutions Inc., Endo Pharmaceuticals Inc, and Par Pharmaceutical hereinafter are collectively referred to as "Endo.")

32. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the U.S., including Texas. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the U.S., including Texas, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

33. Allergan PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis PLC acquired Allergan PLC in March 2015, and the combined company changed its name to Allergan PLC in January 2013. Before that, Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013, later to Actavis PLC in October 2013.

34. Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan PLC (f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.).

35. Actavis Pharma, Inc. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc.

36. Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey.

37. Defendant Allergan Sales, LLC, is incorporated in Delaware and headquartered in Irvine, California. Allergan Sales, LLC is the current New Drug Application ("NDA") holder for Kadian, and in 2016, Allergan Sales, LLC held the Abbreviated New Drug Applications ("ANDAs") for Norco. Allergan Sales, LLC, is the wholly-owned subsidiary of Allergan plc. The Norco ANDAs are currently held by Allergan Pharmaceuticals International Limited, which is incorporated in Ireland.

38. Defendant Allergan USA, Inc. is incorporated in Delaware and headquartered in Madison, New Jersey. Allergan USA, Inc. is currently responsible for Norco and Kadian sales. Allergan USA, Inc. is a wholly-owned subsidiary of Allergan plc.

39. Each of these defendants is owned by Allergan PLC, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan PLC exercises control over and derives a financial benefit from the marketing, sales, and profits of Allergan/Actavis products.

40. Allergan Finance, LLC is a wholly-owned subsidiary of Allergan plc, which markets and sells Allergan plc's drugs in the United States. Allergan plc and Allergan Finance, LLC are collectively referred to herein as "Allergan." Allergan PLC, Allergan Finance, LLC,

Allergan Sales, LLC, Allergan USA, Inc, Actavis PLC, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. hereinafter are referred to collectively as “Actavis.”

41. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the U.S., including Texas. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

42. Defendant Amneal Pharmaceuticals, LLC ("Amneal LLC") is a Delaware limited liability company with its principal place of in New Jersey. Defendant Amneal Pharmaceuticals, Inc. ("API") is a Delaware corporation with its principal place of business in New Jersey. API is the managing member of Amneal LLC and conducts and exercises full control over all activities of Amneal LLC. API and Amneal LLC are referred to herein as "Amneal."

43. At all relevant times, Amneal has sold prescription drugs, including opioids in the United States and Texas, including those in the geographic area served by LOCAL 716.

44. Defendant Assertio Therapeutics, Inc. f/k/a Depomed, Inc. ("Assertio") is a Delaware corporation with its principal place of business in Lake Forest, Illinois. Assertio describes itself as a specialty pharmaceutical company focused on pain and other central nervous system conditions. Assertio develops, markets, and sells prescription drugs in Texas, including the geographic area served by LOCAL 716, and across the United States. Assertio acquired the rights to Nucynta and Nucynta ER for \$1.05 billion from Janssen pursuant to a January 15, 2015, Asset Purchase Agreement. This agreement closed on April 2, 2015. Assertio has since that date, if not before, sold opioids in Texas, including the geographic area served by LOCAL 716.

45. Defendant Abbott Laboratories is an Illinois corporation with its principal place of business in Abbott Park, Illinois. Defendant Abbott Laboratories, Inc. is a subsidiary of Abbott Laboratories, whose principal place of business is also in Abbott Park, Illinois. Defendants Abbott Laboratories and Abbott Laboratories, Inc. are referred to collectively as "Abbott."

46. Abbott was primarily engaged in the promotion and distribution of opioids nationally due to a co-promotional agreement with Purdue. Pursuant to that agreement, between 1996 and 2006, Abbott actively promoted, marketed, and distributed Purdue's opioid products as set forth above.

47. Abbott, as part of the co-promotional agreement, helped turn OxyContin into the largest selling opioid in the nation. Under the co-promotional agreement with Purdue, the more Abbott generated in sales, the higher the reward. Specifically, Abbott received twenty-five to thirty percent (25-30%) of all net sales for prescriptions written by doctors its sales force called on. This agreement was in operation from 1996-2002, following which Abbott continued to receive a residual payment of six percent (6%) of net sales up through at least 2006.

48. With Abbott's help, sales of OxyContin went from a mere \$49 million in its first full year on the market to \$1.2 billion in 2002. Over the life of the co-promotional agreement, Purdue paid Abbott nearly half a billion dollars.

49. Abbott and Purdue's conspiracy with Pharmacy Benefit Managers (PBMs) to drive opioid use is well established. As described in an October 28, 2016, article from Psychology Today entitled *America's Opioid Epidemic*:

Abbott and Purdue actively misled prescribers about the strength and safety of the painkiller [OxyContin]. To undermine the policy of requiring prior authorization, they offered lucrative rebates to middlemen such as Merck Medco [now Express Scripts] and other pharmacy benefits managers on condition that they eased

availability of the drug and lowered co-pays. The records were part of a case brought by the state of West Virginia against both drug makers alleging inappropriate and illegal marketing of the drug as a cause of widespread addiction.... One reason the documents are so troubling is that, in public at least, the drug maker was carefully assuring authorities that it was working with state authorities to curb abuse of OxyContin. Behind the scene, however, as one Purdue official openly acknowledged, the drug maker was "working with Medco (PBM) [now Express Scripts] to try and make parameters [for prescribing] less stringent."¹

50. Mallinckrodt, PLC, an alien company doing business as Mallinckrodt Pharmaceuticals, with its principal place of business in the United States in St. Louis, Missouri. Mallinckrodt, LLC is a Delaware limited liability company, also doing business as Mallinckrodt Pharmaceuticals, with its principal place of business in the United States in Hazelwood, Missouri. Mallinckrodt plc and Mallinckrodt LLC are collectively referred to herein as "Mallinckrodt." Mallinckrodt is one of the largest manufacturers of the generic opioid oxycodone.

51. Cephalon, Janssen, Endo, Actavis, Amneal, Assertio, Mallinckrodt, and Abbott are collectively referred to hereinafter as the "Manufacturer Defendants."

iii. National Retail National Retail Pharmacies Defendants

52. Defendant CVS Health Corporation ("CVS Health") is a Delaware corporation with its principal place of business in Rhode Island at all relevant times to this Complaint.

53. Defendant CVS Pharmacy, Inc. ("CVS Pharmacy") is a Rhode Island corporation with its principal place of business in Rhode Island.

54. CVS Health and CVS Pharmacy are collectively referred to as "CVS." CVS distributed prescription opioids throughout the United States, including Texas and the geographic area served by LOCAL 716.

¹ American Society of Addiction Medicine, *America's Opioid Epidemic – Court released documents show drug makers blocked efforts to curb prescribing*, PSYCHOLOGY TODAY (Oct. 28, 2016), <https://www.psychologytoday.com/blog/side-effects/201610/america-s-opioid-epidemic>.

55. Defendant, the Kroger Co., is an Ohio corporation with its headquarters in Cincinnati, Ohio.

56. Defendant, Kroger Limited Partnership II is an Ohio limited partnership with its principal office located in Columbus, Ohio.

57. The Kroger Co. and Kroger Limited Partnership II are collectively referred to as "Kroger." Kroger operates 2,268 pharmacies in the United States, including in Texas and the geographic area served by LOCAL 716. At all times relevant to this Complaint, Kroger distributed prescription opioids throughout the United States, including in Texas and the geographic area served by LOCAL 716.

58. Defendant Rite Aid Corporation ("Rite Aid") is a Delaware corporation with its principal place of business in Camp Hill, Pennsylvania. At all relevant times to this Complaint, Rite Aid distributed prescription opioids throughout the United States, including in Texas and the geographic area served by LOCAL 716.

59. Defendant Walgreens Boots Alliance Inc. ("Walgreens") is an Illinois corporation with its principal place of business in Deerfield, Illinois. Defendant Walgreen Eastern Co., Inc. ("WEC") is a New York corporation with its principal place of business in Deerfield, Illinois.

60. Walgreens and WEC are collectively referred to herein as "Walgreens." At all times relevant to this Complaint, Walgreens distributed prescription opioids throughout the United States, including in Texas and the geographic area served by LCOAL 716.

61. Defendant Wal-Mart Inc., formerly known as Wal-Mart Stores, Inc. ("Wal-Mart"), is a Delaware corporation with its principal place of business in Arkansas.

62. Defendant, Wal-Mart Stores East, LP, is a Delaware limited partnership with its principal place of business in Arkansas.

63. Wal-Mart, Inc. and Wal-Mart Stores East, LP are collectively referred to as "Wal-Mart." At all times relevant to this Complaint, Wal-Mart distributed prescription opioids throughout the United States, including in Texas and the geographic area served by LOCAL 716.

64. Collectively, Defendants CVS, Kroger, Rite Aid, Walgreens, and Wal-Mart are referred to as "National Retail Pharmacies."

65. The Plaintiff presently lacks information sufficient to specifically identify the true names or capacities, whether individual, corporate or otherwise, of the Defendants sued herein under the fictitious names DOES 1 through 100 inclusive. The Plaintiff will amend this Complaint to show their true names and capacities if and when they are ascertained. The Plaintiff is informed and believes, and on such information and belief alleges, that each of the Defendants named as a DOE is responsible in some manner for the events and occurrences alleged in this Complaint and is liable for the relief sought herein.

JURISDICTION AND VENUE

66. The Plaintiff brings this civil action in *In Re: National Prescription Opiate Litigation*, MDL 2804, and files directly in the Northern District of Ohio as permitted in Paragraph 6(a) of this Court's Case Management Order No. 1 dated April 11, 2018 (Doc. # 232).

67. Jurisdiction of this Court arises under the laws of the United States 28 U.S.C. § 1392 as the parties are citizens of different states and the amount in controversy exceeds \$75,000.00, exclusive of attorney's fees and costs. This Court has supplemental jurisdiction over the Plaintiff's state law claims pursuant to 28 U.S.C. § 1367.

68. Defendants have engaged in conduct and activities over a long time, systematically,

individually, jointly, and severally, in the geographic area served by LOCAL 716 that have caused all of the Plaintiff's damages and all of which form the bases of the causes of action in this Complaint as against Defendants. Defendants have committed multiple torts and breaches within the geographic areas in which LOCAL 716 serves, repeatedly and systematically. Defendants, for a long time, repeatedly and systematically, have substantial contacts and business relationships with LOCAL 716, some or all of which form the basis of the causes of action in this Complaint as against Defendants.

69. The U.S. District Court, Southern District of Texas, has personal jurisdiction over Defendants, each of which has substantial contacts and business dealings throughout by virtue of the distribution, dispensing, and sales of prescription opioids within Texas. All causes of action herein relate to Defendants' wrongful actions, conduct, and omissions within Texas and consequences and damages related to said wrongful actions, conduct, and omissions.

70. Venue is proper in the U.S. District Court, Southern District of Texas because many of the Defendants' acts and omissions that gave rise to the causes of action of this Complaint occurred in this judicial District. Plaintiff states that, but for the Order permitting direct filing into the Northern District of Ohio pursuant to Case Management Order No. 1, dated April 11, 2018, Plaintiff would have filed in the U.S. District Court, Southern District of Texas.

BACKGROUND FACTS

71. Opioid means "opium-like," and the term includes all drugs derived in whole or in part from the opium poppy.

72. The United States Food and Drug Administration's website describes this class of drugs as follows: "Prescription opioids are powerful pain-reducing medications that include prescription oxycodone, hydrocodone, and morphine, among others, and have both benefits as well

as potentially serious risks. These medications can help manage pain when prescribed for the right condition and when used properly. But when misused or abused, they can cause serious harm, including addiction, overdose, and death."

73. Prescription opioids with the highest potential for addiction are categorized under Schedule II of the Controlled Substances Act. They include non-synthetic derivatives of the opium poppy (such as codeine and morphine, which are also called "opiates"), partially synthetic derivatives (such as hydrocodone and oxycodone), or fully synthetic derivatives (such as fentanyl and methadone).

74. Before the epidemic of Defendants' prescription opioids, the generally accepted standard of medical practice was that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

Manufacturer Defendants' Wrongful Conduct

75. To establish and exploit the lucrative market of chronic pain patients, each Manufacturer Defendant developed a well-funded, sophisticated, and deceptive marketing and/or distribution scheme targeted at consumers and physicians. These Defendants used direct marketing, as well as veiled advertising by seemingly independent third parties to spread false and deceptive statements about the risks and benefits of long-term opioid use – statements that created the "new" market for prescription opioids, upended the standard medical practice, and benefited other Defendants and opioid manufacturers. These statements were unsupported by and contrary

to the scientific evidence. These statements were also contrary to pronouncements by and guidance from the FDA and CDC based on that evidence. They also targeted susceptible prescribers and vulnerable patient populations, including those in the geographic area served by LOCAL 716.

76. The Manufacturer Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients in Texas. Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout geographic areas served by LOCAL 716.

77. The Manufacturer Defendants' direct and branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs, misleadingly implying that the drug would provide long-term pain relief and functional improvement. While Endo agreed in 2015-16 to stop these particularly misleading representations in New York, they continued to disseminate them in Texas.

78. The Manufacturer Defendants also promoted the use of opioids for chronic pain through "detailers" – sophisticated and specially trained sales representatives who visited individual doctors and medical staff and fomented small-group speaker programs. In 2014, for instance, these Defendants spent almost \$200 million on detailing branded opioids to doctors.

79. The FDA has cited at least one of these Defendants for deceptive promotions by its detailers and direct-to-physician marketing. In 2010 an FDA-mandated "Dear Doctor" letter required Actavis to inform doctors that "Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian]," including the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid[s]

have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion.”

80. The Manufacturer Defendants invited doctors to participate, for payment and other remuneration, on and in speakers’ bureaus and programs paid for by these Defendants. These speaker programs were designed to provide incentives for doctors to prescribe opioids, including recognition and compensation for being selected as speakers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by these Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Defendants’ prior misrepresentations about the risks and benefits of opioids.

81. The Manufacturer Defendants’ detailing to doctors was highly effective in the national proliferation of prescription opioids. Defendants used sophisticated data mining and intelligence to track and understand the rates of initial prescribing and renewal by individual doctors, allowing specific and individual targeting, customizing, and monitoring of their marketing.

82. The Manufacturer Defendants have had unified marketing plans and strategies from state to state, including Texas. This unified approach ensures that Defendants’ messages were and are consistent and effective across all their marketing efforts.

83. The Manufacturer Defendants deceptively marketed opioids in Texas through unbranded advertising that promoted opioid use generally, yet silent as to a specific opioid. This advertising was ostensibly created and disseminated by independent third parties, but funded, directed, coordinated, edited, and distributed, in part or whole, by these Defendants and their public relations firms and agents.

84. The Manufacturer Defendants used putative third-party, unbranded advertising to avoid regulatory scrutiny as such advertising is not submitted to or reviewed by the FDA. These Defendants used third-party, unbranded advertising to create the false appearance that the deceptive messages came from an independent and objective source.

85. The Manufacturer Defendants' deceptive unbranded marketing also contradicted their branded materials reviewed by the FDA.

86. The Manufacturer Defendants marketed opioids through a small circle of doctors who were vetted, selected, funded, and promoted by these Defendants because their public positions supported the use of prescription opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs." These Defendants paid KOLs to serve in a number of doctor-facing and public-facing capacities, all designed to promote a pro-opioid message and to promote the opioid industry pipeline, from manufacture to distribution to retail.

87. These Defendants entered into and/or benefitted from arrangements with seemingly unbiased and independent organizations or groups that generated treatment guidelines, unbranded materials, and programs promoting chronic opioid therapy, including the American Pain Society ("APS"), American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), American Society of Pain Education ("ASPE"), National Pain Foundation ("NPF"), and Pain & Policy Studies Group ("PPSG").

88. The Manufacturer Defendants collaborated, through the aforementioned organizations and groups, to spread deceptive messages about the risks and benefits of long-term opioid therapy.

89. To convince doctors and patients in Texas that opioids can and should be used to treat chronic pain, these Defendants had to persuade them that long-term opioid use is both safe

and helpful. Knowing that they could do so only by deceiving those doctors and patients about the risks and benefits of long-term opioid use, these Defendants made claims that were not supported by or were contrary to the scientific evidence and which were contradicted by data.

90. To convince doctors and patients that opioids are safe, the Manufacturer Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations – which are described below – reinforced each other and created the dangerously misleading impression that: (a) starting patients on opioids was low-risk because most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed; (b) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (c) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (d) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. Defendants have not only failed to correct these misrepresentations, but they also continue to make them today.

91. The Manufacturer Defendants falsely claimed that the risk of opioid addiction is low and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of opioids. Some examples of these false and deceptive claims by opioid manufacturers are: (a) Actavis employed a patient education brochure that falsely claimed opioid addiction is “less likely if you have never had an addiction problem”; (b) Cephalon sponsored APF’s *Treatment Options: A Guide for People Living with Pain*, falsely claiming that addiction is rare and limited to extreme cases of unauthorized doses; (c) Endo sponsored a website, Painknowledge.com, which falsely claimed

that “[p]eople who take opioids as prescribed usually do not become addicted”; (d) Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: “most people do not develop an addiction problem”; (e) Janssen distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* which described as “myth” the claim that opioids are addictive; and (f) a Janssen website falsely claimed that concerns about opioid addiction are “overestimated.”

92. These claims are contrary to longstanding scientific evidence, as the FDA and CDC have conclusively declared. As noted in the 2016 CDC Guideline endorsed by the FDA, there is “extensive evidence” of the “possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction]).” The Guideline points out that “[o]pioid pain medication use presents serious risks, including . . . opioid use disorder” and that “continuing opioid therapy for three (3) months substantially increases risk for opioid use disorder.”

93. The FDA further exposed the falsity of the Manufacturer Defendants’ claims about the low risk of addiction when it announced changes to the labels for certain opioids in 2013 and for other opioids in 2016. In its announcements, the FDA found that “most opioid drugs have ‘high potential for abuse’” and that opioids “are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death.” According to the FDA, because of the “known serious risks” associated with long-term opioid use, including “risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death,” opioids should be used only “in patients for whom alternative treatment options” like non-opioid drugs have failed. The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction “can occur in patients appropriately prescribed [opioids].”

94. The State of New York, in a 2016 settlement agreement with Endo, found that opioid “use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder.” Endo had claimed on its www.opana.com website that “[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted,” but the State of New York found no evidence for that statement. Consistent with this, Endo agreed not to “make statements that . . . opioids generally are non-addictive” or “that most patients who take opioids do not become addicted” in New York. This agreement, however, did not extend to Texas.

95. The Manufacturer Defendants falsely instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Defendants called this phenomenon “pseudo-addiction” – a term used by Dr. Russell Portenoy, a KOL for Cephalon, Endo, and Janssen. Defendants falsely claimed that pseudo-addiction was substantiated by scientific evidence. Some examples of these deceptive claims are: (a) Cephalon sponsored *Responsible Opioid Prescribing*, which taught that behaviors such as “requesting drugs by name,” “demanding or manipulative behavior,” seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudo-addiction, rather than true addiction; (b) Janssen sponsored, funded, and edited the *Let’s Talk Pain* website, which in 2009 stated: “pseudo-addiction . . . refers to patient behaviors that may occur when pain is under-treated”; and (c) Endo sponsored a National Initiative on Pain Control (NIPC) CME program titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudo-addiction by teaching that a patient’s aberrant behavior was the result of untreated pain.

96. The 2016 CDC Guideline rejects the concept of pseudo-addiction, explaining that “[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use,” and that physicians should “reassess[] pain and function within 1 month” in order to decide whether to “minimize risks of long-term opioid use by discontinuing opioids” because the patient is “not receiving a clear benefit.”

97. The Manufacturer Defendants falsely instructed doctors and patients that addiction risk screening tools, patient agreements, urine drug screens, and similar strategies were very effective to identify and safely prescribe opioids to even those patients predisposed to addiction. These misrepresentations were reckless because Manufacturer Defendants directed them to general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Manufacturer Defendants’ misrepresentations were intended to make doctors more comfortable in prescribing opioids. Some examples of these deceptive claims are an Endo supplement in the *Journal of Family Practice* that emphasized the effectiveness of screening tools to avoid addictions.

98. The 2016 CDC Guideline exposes the falsity of these misrepresentations, noting that there are no studies assessing the effectiveness of risk mitigation strategies – such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse – “for improving outcomes related to overdose, addiction, abuse, or misuse.” The Guideline emphasizes that available risk screening tools “show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse” and counsels that doctors “should not overestimate the ability of these tools to rule out risks from long-term opioid therapy.”

99. To underplay the risk and impact of addiction, and make doctors feel more comfortable starting patients on opioids, Manufacturer Defendants falsely claimed that opioid dependence can easily be solved by tapering, that opioid withdrawal was not difficult, and that there were no problems in stopping opioids after long-term use.

100. A CME sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms could be avoided by tapering a patient's opioid dose by up to 20% for a few days.

101. Manufacturer Defendants deceptively minimized the significant symptoms of opioid withdrawal – which, as explained in the 2016 CDC Guideline, include drug cravings, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction – and grossly understated the difficulty of tapering, particularly after long-term opioid use. The 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed should be “limit[ed]” to “minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms,” because “physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days.” The Guideline further states that “tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence” and highlights the difficulties, including the need to carefully identify “a taper slow enough to minimize symptoms and signs of opioid withdrawal” and to “pause[] and restart[]” tapers depending on the patient's response. The CDC also acknowledges the lack of any “high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued.”

102. The Manufacturer Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk of addiction and other health consequences, and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up a tolerance, and lower dosages did not provide pain relief. For example: (a) an Actavis patient brochure stated - "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction"; (b) Cephalon sponsored *APF's Treatment Options: A Guide for People Living with Pain*, claiming that some patients need larger doses of opioids, with "no ceiling dose" for appropriate treatment of severe, chronic pain; (c) an Endo website, painknowledge.com, claimed that opioid dosages may be increased until "you are on the right dose of medication for your pain"; (d) an Endo pamphlet *Understanding Your Pain: Taking Oral Opioid Analgesics*, stated "The dose can be increased. . . . You won't 'run out' of pain relief"; and (e) a Janssen patient education guide *Finding Relief: Pain Management for Older Adults* listed dosage limitations as "disadvantages" of other pain medicines yet omitted any discussion of risks of increased opioid dosages.

103. These and other representations conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages." The CDC states that "there is an increased risk for opioid use disorder, respiratory

depression, and death at higher dosages.” That is why the CDC advises doctors to “avoid increasing dosages” above 90 morphine milligram equivalents per day.

104. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged “that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events.” For example, the FDA noted that studies “appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality.”

105. Manufacturer Defendants’ deceptive marketing of the so-called abuse-deterrent properties of some of their opioids created false impressions that these opioids can curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive.

106. Manufacturer Defendants have made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter abuse. For example, Endo’s advertisements for the 2012 reformulation of Opana ER falsely claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. The FDA warned in a 2013 letter that there was no evidence Endo’s design “would provide a reduction in oral, intranasal or intravenous abuse.” Moreover, Endo’s own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed.

107. In a 2016 settlement with the State of New York, Endo agreed not to make statements in New York that Opana ER was “designed to be, or is crush resistant.” The State found those statements false and deceptive because there was no difference in the ability to extract the narcotic from Opana ER. Similarly, the 2016 CDC Guideline states that “[n]o studies” support the notion that “abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing

abuse,” noting that the technologies – even when they work – “do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes.”

108. These numerous, longstanding misrepresentations minimizing the risks of long-term opioid use persuaded doctors and patients to discount or ignore the true risks. Manufacturer Defendants also had to persuade them that there was a significant upside to long-term opioid use. But as the 2016 CDC Guideline makes clear, there is “insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain.” In fact, the CDC found that “[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials \leq 6 weeks in duration)” and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was “not aware of adequate and well-controlled studies of opioids use longer than 12 weeks.” Despite this, Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence. Not only have Defendants failed to correct these false and deceptive claims, but they also continue to make them today.

109. For example, the Manufacturer Defendants falsely claimed that long-term opioid use improved patients’ function and quality of life, including the following misrepresentations: (a) an Actavis advertisement claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve “stress on your body and your mental health,” and help patients enjoy their lives; (b) an Endo advertisement that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks, portraying seemingly healthy, unimpaired persons; (c) a Janssen patient education guide *Finding Relief: Pain Management for Older Adults* stated as “a

fact” that “opioids may make it easier for people to live normally” such as sleeping peacefully, working, recreation, sex, walking, and climbing stairs; (d) *Responsible Opioid Prescribing*, by Cephalon and Endo taught that relief of pain by opioids, by itself, improved patients’ function; (e) Cephalon sponsored APF’s *Treatment Options: A Guide for People Living with Pain* counseling patients that opioids “give [pain patients] a quality of life we deserve”; (f) Endo’s NIPC website *painknowledge.com* claimed that with opioids, “your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse”; (g) Endo CMEs titled *Persistent Pain in the Older Patient* claimed that chronic opioid therapy had been “shown to reduce pain and improve depressive symptoms and cognitive functioning”; (h) Janssen sponsored, funded, and edited a website, *Let’s Talk Pain*, in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to “continue to function”; and (i) Cephalon’s, Endo’s, and Janssen’s sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

110. These claims find no support in the scientific literature. The 2016 CDC Guideline concluded that “there is no good evidence that opioids improve pain or function with long-term use, and . . . complete relief of pain is unlikely.” The CDC reinforced this conclusion throughout its 2016 Guideline:

111. “No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later . . .”

112. “Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy.”

113. “[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia.”

114. The CDC also noted that the risks of addiction and death “can cause distress and inability to fulfill major role obligations.” As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

115. The 2016 CDC Guideline was not the first time a federal agency repudiated the Manufacturer Defendants’ claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis that “[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient’s work, physical and mental functioning, daily activities, or enjoyment of life.” In 2008, the FDA sent a warning letter to an opioid manufacturer, making it clear “that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience.”

116. The Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort “in patients for which alternative

treatment options” like non-opioid drugs “are inadequate.” The 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

117. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid-tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for or has been shown to be safe or effective for chronic pain.

118. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of “serious and life-threatening adverse events” and abuse – which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.

119. Despite this, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example: (a) Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of *Pain Medicine News* in 2009. The CME instructed doctors that “clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility” and recommended Actiq and Fentora for patients with

chronic pain; (b) Cephalon's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain; and (c) in December 2011, Cephalon widely disseminated a journal supplement entitled "*Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)*" to *Anesthesiology News*, *Clinical Oncology News*, and *Pain Medicine News* – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain" – and not just cancer pain.

120. Cephalon's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

121. Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the State of New York found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

122. Mallinckrodt, one of the largest manufacturers of the generic opioid oxycodone, recently agreed to pay a \$35 million penalty to resolve allegations by the U.S. Department of Justice that it failed to report suspicious drug orders. This is a record settlement of claims that a pharmaceutical drug manufacturer failed to properly notify the U.S. Drug Enforcement Administration of suspicious orders for drugs such as oxycodone. Former U.S. Attorney General

Jeff Sessions said “Mallinckrodt’s actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street.” According to the Justice Department, from 2008 to 2011, Mallinckrodt supplied distributors increasingly excessive amounts of oxycodone pills without notifying the DEA of the suspicious orders. Those distributors, in turn, supplied the drugs to various U.S. pharmacies and pain clinics, the Justice Department said. Mallinckrodt, however, continues to deny culpability to the public and the medical community. Michael-Bryant Hicks, Mallinckrodt’s general counsel, said the company chose to settle “to eliminate the uncertainty, distraction and expense of litigation and to allow the company to focus on meeting the important needs of its patients and customers.”

123. As a part of their deceptive marketing scheme, the Manufacturer Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the U.S., including in Texas and the geographic served by LOCAL 716. For example, these Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept Defendants’ misrepresentations.

124. The Manufacturer Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. These Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observes that existing evidence shows that elderly patients taking opioids suffer from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse drug effects and interactions. The Guideline,- therefore, concludes that there are “special risks of long-term opioid use for elderly patients” and

recommends that doctors use “additional caution and increased monitoring” to minimize the risks of opioid use in elderly patients. The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids.

125. The Manufacturer Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and deceptive. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned these Defendants of this, and these Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on the medical evidence that conclusively expose the known falsity of Defendants’ misrepresentations, and Endo recently entered agreements prohibiting it from making some of the same misrepresentations described in this Complaint in New York.

126. Moreover, at all times relevant to this Complaint, the Manufacturer Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, the Manufacturer Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. These Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the

accuracy and integrity of Defendants' false and deceptive statements about the risks and benefits of long-term opioid use for chronic pain.

127. The Manufacturer Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. These Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, fake independent groups, and public relations companies that were not, and have not yet become public. For example, painknowledge.org, which is run by the NIPC, did not disclose Endo's involvement. Other Manufacturer Defendants, such as Janssen, ran similar websites that masked their own direct role.

128. Finally, the Manufacturer Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. These Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The lack of support for these Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could it have been detected by LOCAL 716.

129. Thus, the Manufacturer Defendants successfully concealed from the medical community, patients, and health care payers facts sufficient to arouse suspicion of the claims that LOCAL 716 now asserts. LOCAL 716 did not know of the existence or scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

130. The Manufacturer Defendants' misrepresentations deceived doctors and patients about the risks and benefits of long-term opioid use. Studies also reveal that many doctors and

patients are not aware of or do not understand these risks and benefits. Indeed, patients often report that they were not warned they might become addicted to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive.

131. The Manufacturer Defendants' deceptive marketing scheme caused and continues to cause doctors in Texas, and specifically in the geographic area served by LOCAL 716 to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent these Defendants' deceptive marketing scheme, these doctors would not have prescribed as many opioids. These Defendants' deceptive marketing scheme also caused and continues to cause patients to purchase and use opioids for their chronic pain believing they are safe and effective. Absent these Defendants' deceptive marketing scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients using opioids would be using less of them.

132. The Manufacturer Defendants' deceptive marketing has caused and continues to cause the prescribing and use of opioids to explode. Indeed, this dramatic increase in opioid prescriptions and use corresponds with the dramatic increase in Defendants' spending on their deceptive marketing scheme. Defendants' spending on opioid marketing totaled approximately \$91 million in 2000. By 2011, that spending had tripled to \$288 million.

133. The escalating number of opioid prescriptions written by doctors who were deceived by the Manufacturer Defendants' deceptive marketing scheme was the cause of a correspondingly dramatic increase in opioid addiction, overdose, and death throughout the U.S., including Texas, and in the geographic area served by LOCAL 716. In August 2016, the U.S. Surgeon General published an open letter to be sent to physicians nationwide, enlisting their help

in combating this “urgent health crisis” and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the “devastating” results that followed, had “coincided with heavy marketing to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain.”

134. Scientific evidence demonstrates a strong correlation between opioid prescriptions and opioid abuse. In a 2016 report, the CDC explained that “[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses.” Patients receiving prescription opioids for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical “to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity.”

135. Contrary to the Manufacturer Defendants’ misrepresentations, most opioid addiction begins with legitimately *prescribed* opioids, and therefore could have been prevented had Defendants’ representations to prescribers been truthful. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from pill mills, drug dealers or the internet. Numerous doctors and substance abuse counselors note that many of their patients, who misuse or abuse opioids started with legitimate prescriptions, confirming the important role that doctors’ prescribing habits have played in the opioid epidemic.

Distributor Defendants’ Wrongful Conduct

136. The supply chain for prescription opioids begins with the manufacture and packaging of the pills. The manufacturers then transfer the pills to distribution companies, including Defendants Cardinal, McKesson, and AmerisourceBergen, which together account for 85-90 % of all revenues from drug distribution in the United States, an estimated \$378.4 billion in

2015. The distributors then supply opioids to pharmacies, doctors, and other healthcare providers, which then dispense the drugs to patients.

137. Manufacturer Defendants and Distributor Defendants share the responsibility for controlling the availability of prescription opioids. Opioid “diversion” occurs whenever the supply chain of prescription opioids is broken, and the drugs are transferred from a legitimate channel of distribution or use to an illegitimate channel of distribution or use. Diversion can occur at any point in the opioid supply chain, including at the pharmacy level, when prescriptions are filled for any reason other than a legitimate medical purpose.

138. For example, at the wholesale level of distribution, diversion occurs whenever distributors allow opioids to be lost or stolen in transit, or when distributors fill suspicious orders of opioids from buyers, retailers, or prescribers. Suspicious orders include orders of unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern, and/or orders of unusual frequency and duration.

139. Diversion occurs at the pharmacies, including whenever a pharmacist fills a prescription despite having reason to believe it was not issued for a legitimate medical purpose or not in the usual course of practice. Some of the signs that a prescription may have been issued for an illegitimate medical purpose include when the patient seeks to fill multiple prescriptions from different doctors (a/k/a doctor shopping), when they travel great distances between the doctor or their residence and the pharmacy to get the prescription filled, when they present multiple prescriptions for the largest dose of more than one controlled substance, or when there are other “red flags” surrounding the transaction. These signs or “red flags” should trigger closer scrutiny of the prescriptions by the pharmacy and lead to a decision that the patient is not seeking the medication for purposes to treat a legitimate medical condition. In addition to diversion via

prescription, opioids are also diverted from retail outlets when stolen by employees or others.

140. Diversion occurs through the use of stolen or forged prescriptions at pharmacies, or the sale of opioids without prescriptions, including patients seeking prescription opioids under false pretenses.

141. Opioid diversion occurs in the United States at an alarming rate. In recent years, the number of people who take prescription opioids for non-medical purposes is greater than the number of people who use cocaine, heroin, hallucinogens, and inhalants combined.

142. Every year, millions of people in the United States misuse and abuse opioid pain relievers that can lead to addiction, overdose and death.

143. Within the last 20 years, the abuse of prescription narcotic pain relievers has emerged as a public health crisis in the United States. Overdose deaths involving prescription opioids are at epidemic proportions, quadrupling since 1999, concomitant with sales of these prescriptions.

144. In 2011 overdose deaths from prescription opioids reached 16,917 people. In 2014 18,893 people died from a prescription opioid-related overdose. In 2015, the number of deaths increased to 22,598, even despite increased public health announcements.

145. The dramatic rise in heroin use in recent years is a direct result of prescription opioid diversion. The strongest risk factor for a heroin use disorder is prescription opioid use. In one national study covering the period 2008 to 2010, 77.4% of the participants reported using prescription opioids before initiating heroin use. Another study revealed that 75% of those who began their opioid abuse in the 2000s started with a prescription opioid. The CDC has reported that people who are dependent on prescription opioid painkillers are 40 times more likely to become dependent on heroin. Heroin deaths are on a tragic upswing: In 2015, over 12,989 people

died from heroin overdose-up more than 20% from approximately 10,574 overdose deaths in 2014.

146. LOCAL 716 has taken proactive measures to fight against prescription opioid abuse.

147. LOCAL 716, uniquely and significantly, has been damaged by the effects of the Distributor Defendants' opioid diversion.

148. The CDC reports that for every opioid-related death, there are, on average 10 hospital admissions for abuse, 26 emergency department visits for misuse, 108 people who are dependent on opioids, and 733 non-medical users.

149. Defendants' opioid diversion has caused and will continue to cause LOCAL 716 damages, including greater expenditures by LOCAL 716.

150. Distributor Defendants have a duty to exercise reasonable care under the circumstances. This involves a duty not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative conduct, and thereafter realizes or should realize that such conduct has created an unreasonable risk of harm to another, is under a duty to exercise reasonable care to prevent the threatened harm.

151. In addition to having common law duties, the Distributor Defendants are governed by the statutory requirements of the Controlled Substances Act ("CSA"), 21 U.S.C. § 801 et seq. and its implementing regulations. These requirements were enacted to protect society from the harms of drug diversion. The Distributor Defendants' violations of these requirements show that they failed to meet the relevant standard of conduct that society expects from them. The Distributor Defendants' repeated, unabashed, and prolific violations of these requirements show that they have acted in total reckless disregard.

152. By violating the CSA, the Distributor Defendants are also liable under the

applicable state common law as herein alleged.

153. The CSA creates a legal framework for the distribution and dispensing of controlled substances. Congress passed the CSA partly out of a concern about "the widespread diversion of [controlled substances] out of legitimate channels into the illegal market." H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566, 4572.

154. Accordingly, the CSA acts as a system of checks and balances from the manufacturing level through the delivery of the pharmaceutical drug to the patient or ultimate user. Every person or entity that manufactures, distributes, or dispenses opioids must obtain a "registration" with the DEA. Registrants at every level of the supply chain must fulfill their obligations under the CSA, otherwise controlled substances move from the legal to the illicit marketplace, and there is enormous potential for harm to the public.

155. All opioid distributors are required to maintain effective controls against opioid diversion. They are also required to create and use a system to identify and report downstream suspicious orders of controlled substances to law enforcement. Suspicious orders include orders of unusual size, orders deviating substantially from the normal pattern, and orders of unusual frequency. To comply with these requirements, distributors must know their customers, report suspicious orders, conduct due diligence, and terminate orders if there are indications of diversion.

156. To prevent unauthorized users from obtaining opioids, the CSA creates a distribution monitoring system for controlled substances, including registration and tracking requirements imposed upon anyone authorized to handle controlled substances. The DEA's Automation of Reports and Consolidation Orders System ("ARCOS") is an automated drug reporting system that records and monitors the flow of Schedule II controlled substances from the point of manufacture through commercial distribution channels to the point of sale. ARCOS

accumulates data on the distribution of controlled substances, acquisition transactions, and distribution transactions, which are summarized into reports used by the DEA to identify any diversion of controlled substances into illicit channels of distribution. Each person or entity that is registered to distribute ARCOS Reportable controlled substances must report acquisition and distribution transactions to the DEA.

157. Acquisition and distribution transaction reports must provide data on each acquisition to inventory (identifying whether it is, e.g., by purchase or transfer, return from a customer, or supply by the Federal Government) and each reduction from inventory (identifying whether it is, e.g., by sale or transfer, theft, destruction or seizure by Government agencies) for each ARCOS Reportable controlled substance. 21 U.S.C. § 827(d) (l); 21 C.F.R. §§ 1304.33(e), (d). Inventory that has been lost or stolen must also be reported separately to the DEA within one business day of discovery of such loss or theft.

158. In addition to filing acquisition/distribution transaction reports, each registrant is required to maintain a complete, accurate, and current record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of. 21 U.S.C. §§ 827(a)(3), 1304.2l(a), 1304.22(b). It is unlawful for any person to negligently fail to abide by the recordkeeping and reporting requirements.

159. To maintain registration, distributors must also maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific and industrial channels. When determining if a distributor has provided effective controls, the DEA Administrator refers to the security requirements set forth in §§ 130 1.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. 21 CFR § 1301.71.

160. For years the Distributor Defendants have known of the problems and consequences of opioid diversion in the supply chain, yet have committed repeated violations of the laws and regulations of the United States as cited above, consequently making them liable under the applicable state common law.

161. To combat the problem of opioid diversion, the DEA has provided guidance to distributors on the requirements of suspicious order reporting in numerous venues, publications, documents, and final agency actions. Since 2006, the DEA has conducted one-on-one briefings with distributors regarding their downstream customer sales, due diligence responsibilities, and legal and regulatory responsibilities (including the responsibility to know their customers and report suspicious orders to the DEA). The DEA provided distributors with data on controlled substance distribution patterns and trends, including data on the volume of orders, frequency of orders, and percentage of controlled vs. non-controlled purchases. The distributors were given case studies, legal findings against other registrants, and ARCOS profiles of their customers whose previous purchases may have reflected suspicious ordering patterns. The DEA emphasized the "red flags" distributors should look for to identify potential diversion.

162. Since 2007, the DEA has hosted no less than five conferences to provide opioid distributors with updated information about diversion trends. The Defendant Distributors attended at least one of these conferences, which allowed for questions and discussions. The DEA has participated in numerous meetings and events with the legacy Healthcare Distribution Management Association (HDMA), now known as the Healthcare Distribution Alliance (HAD), an industry trade association for wholesalers and distributors. DEA representatives have provided guidance to the association concerning suspicious order monitoring, and the association has published guidance documents for its members on suspicious order monitoring, reporting

requirements, and the diversion of controlled substances.

163. On September 27, 2006 and December 27, 2007, the DEA Office of Diversion Control sent letters to all registered distributors providing guidance on suspicious order monitoring of controlled substances and the responsibilities and obligations of the registrant to conduct due diligence on controlled substance customers as part of a program to maintain effective controls against diversion.

164. The September 27, 2006 letter reminded registrants that they were required by law to exercise due diligence to avoid filling orders that could be diverted into the illicit market. The DEA explained that as part of the legal obligation to maintain effective controls against diversion, the distributor was required to exercise due care in confirming the legitimacy of each and every order prior to filling. It also described circumstances that could be indicative of diversion including ordering excessive quantities of a limited variety of controlled substances while ordering few if any other drugs; disproportionate ratio of ordering controlled substances versus non-controlled prescription drugs; the ordering of excessive quantities of a limited variety of controlled substances in combination with lifestyle drugs; and ordering the same controlled substance from multiple distributors. The letter went on to describe what questions should be answered by a customer when attempting to make a determination if the order is indeed suspicious.

165. On December 27, 2007, the Office of Diversion Control sent a follow-up letter to DEA registrants providing guidance and reinforcing the legal requirements outlined in the September 2006 correspondence. The letter reminded registrants that suspicious orders must be reported when discovered and monthly transaction reports of excessive purchases did not meet the regulatory criteria for suspicious order reporting. The letter also advised registrants that they must perform an independent analysis of a suspicious order prior to the sale to determine if the controlled

substances would likely be diverted, and that filing a suspicious order and then completing the sale does not absolve the registrant from legal responsibility. Finally, the letter directed the registrant community to review a recent DEA action that addressed criteria in determining suspicious orders and their obligation to maintain effective controls against diversion.

166. The Distributor Defendants' own industry group, the Healthcare Distribution Management Association, published Industry Compliance Guidelines titled "Reporting Suspicious Orders and Preventing Diversion of Controlled Substances," emphasizing the critical role of each member of the supply chain in distributing controlled substances.

167. These industry guidelines stated: "At the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers."

168. Opioid distributors have admitted to the magnitude of the problem and, at least superficially, their legal responsibilities to prevent diversion. They have made statements assuring the public they are supposedly undertaking a duty to curb the opioid epidemic.

169. For example, a Cardinal executive claimed that Cardinal uses "advanced analytics" to monitor its supply chain. He further extolled that Cardinal was "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any *outside* criminal activity." (emphasis added).

170. McKesson has publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders" and claimed it is "deeply passionate about curbing the opioid epidemic in our Country."

171. These assurances, on their face, of identifying and eliminating criminal activity and curbing the opioid epidemic create a duty for the Distributor Defendants to take reasonable

measures to do just that.

172. In addition to the obligations imposed by law, through their own words, representations, and actions, the Distributor Defendants have voluntarily undertaken a duty to protect the public at large against diversion from their supply chains and to curb the opioid epidemic. In this voluntary undertaking, the Distributor Defendants have miserably and negligently failed.

173. The Distributor Defendants have knowingly or negligently allowed diversion. Their wrongful conduct and inaction have resulted in numerous civil fines and other penalties recovered by state and federal agencies- including actions by the DEA related to violations of the Controlled Substances Act.

174. In 2008, Cardinal paid a \$34 million penalty to settle allegations about opioid diversion taking place at seven of its warehouses in the United States. In 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states. In December 2016, a Department of Justice press release announced a multi-million-dollar settlement with Cardinal for violations of the Controlled Substances Act. In connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to certain pharmacies.

175. In May 2008, McKesson entered into a settlement with the DEA on claims that McKesson failed to maintain effective controls against the diversion of controlled substances. McKesson allegedly failed to report suspicious orders from rogue Internet pharmacies around the Country, resulting in millions of doses of controlled substances being diverted. McKesson agreed to pay a \$13.25 million civil fine. McKesson also was supposed to implement tougher controls regarding opioid diversion. McKesson utterly failed. McKesson's system for detecting "suspicious

orders" from pharmacies was so ineffective and dysfunctional that at one of its facilities in Colorado between 2008 and 2013, it filled more than 1.6 million orders, for tens of millions of controlled substances, but it reported just 16 orders as suspicious, all from a single consumer. In 2015, McKesson was in the middle of allegations concerning its "suspicious order reporting practices for controlled substances." In early 2017, it was reported that McKesson agreed to pay \$150 million to the government to settle certain opioid diversion claims that it allowed drug diversion at 12 distribution centers in 11 states.

176. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies. Again in 2012, AmerisourceBergen was implicated for failing to protect against diversion of controlled substances into non-medically necessary channels. It has been reported that the U.S. Department of Justice has subpoenaed AmerisourceBergen for documents in connection with a grand jury proceeding seeking information on the company's "program for controlling and monitoring diversion of controlled substances into channels other than for legitimate medical, scientific and industrial purposes."

177. Henry Schein, too, is a repeat offender. Since the company's inception, it has been subjected to repeated disciplinary actions across the United States for its sale and/or distribution of dangerous drugs to persons or facilities not licensed or otherwise authorized to possess such drugs.

178. In 2014, Henry Schein Animal Health was investigated by the State of Ohio Board of Pharmacy due to its sale/distribution of dangerous wholesale drugs to an entity not holding a valid Ohio license. It reached a settlement with the Ohio Board of Pharmacy related to this investigation in 2015.

179. Records from a disciplinary proceeding against a Wisconsin-licensed medical practitioner reveal that from May 2005 through September 2006, Henry Schein continued to deliver opioids to the provider, despite the fact that his license had been suspended for inappropriate prescribing of opioids.

180. Relying upon state laws and regulations, various State Boards of Pharmacy have directly disciplined the wholesale distributors of prescription opioids for failure to prevent diversion, a duty recognized under state laws and regulations.

181. Although distributors have been penalized by law enforcement authorities, these penalties have not changed their conduct. They pay fines as a cost of doing business in an industry that generates billions of dollars in revenue and profit.

182. The Distributor Defendants have the ability and owe the duty to prevent opioid diversion, which presented a known or foreseeable risk of damage to LOCAL 716.

183. The Distributor Defendants have supplied massive quantities of prescription opioids in and around the geographic areas served by LOCAL 716 with the actual or constructive knowledge that the opioids were ultimately being consumed by citizens for non-medical purposes. Many of these shipments should have been stopped or investigated as suspicious orders, but the Distributor Defendants negligently or intentionally failed to do so.

184. Each Distributor Defendant knew or should have known that the amount of the opioids that it allowed to flow into the geographic areas served by LOCAL 716 was far in excess of what could be consumed for medically-necessary purposes in the relevant communities (especially given that each Distributor Defendant knew it was not the only opioid distributor servicing those communities).

185. The Distributor Defendants negligently or intentionally failed to adequately control

their supply lines to prevent diversion. A reasonably-prudent distributor of Schedule II controlled substances would have anticipated the danger of opioid diversion and protected against it by, for example, taking greater care in hiring, training, and supervising employees; providing greater oversight, security, and control of supply channels; looking more closely at the pharmacists and doctors who were purchasing large quantities of commonly-abused opioids in amounts greater than the populations in those areas would warrant; investigating demographic or epidemiological facts concerning the increasing demand for narcotic painkillers in and around the geographic area served by LOCAL 716; providing information to pharmacies and retailers about opioid diversion; and in general, simply following applicable statutes, regulations, professional standards, and guidance from government agencies and using a little bit of common sense.

186. On information and belief, the Distributor Defendants made little to no effort to visit the pharmacies servicing participants of LOCAL 716 and in the geographic area served by its funds to perform due diligence inspections to ensure that the controlled substances the Distributors Defendants had furnished were not being diverted to illegal uses.

187. On information and belief, the compensation the Distributor Defendants provided to certain of their employees was affected, in part, by the volume of their sales of opioids to pharmacies and other facilities servicing the participants of LOCAL 716 and in the geographic area served by its fund, thus improperly creating incentives that contributed to and exacerbated opioid diversion and the resulting epidemic of opioid abuse.

188. It was reasonably foreseeable to the Distributor Defendants that their conduct in flooding the member market of LOCAL 716 and in the geographic area served by its fund with highly-addictive opioids would allow opioids to fall into the hands of children, addicts, criminals, and other unintended users.

189. It is reasonably foreseeable to the Distributor Defendants that, when unintended users gain access to opioids, tragic preventable injuries will result, including illnesses, overdoses, and death. It is also reasonably foreseeable that the costs of these injuries will be shouldered by LOCAL 716.

190. The Distributor Defendants knew or should have known that the opioids being diverted from their supply chains would contribute to the opioid costs of LOCAL 716, and would create access to opioids by unauthorized users, which, in turn, perpetuates the cycle of illnesses, demand, illegal transactions, economic ruin, and human tragedy.

191. The Distributor Defendants knew or should have known that a substantial amount of the opioids dispensed to patients of LOCAL 716 and in the geographic area served by its hospitals were being dispensed based on invalid or suspicious prescriptions. It is foreseeable that filling suspicious orders for opioids will cause harm to individual pharmacy customers, third-parties, and LOCAL 716.

192. The Distributor Defendants were aware of widespread prescription opioid abuse of persons who would become participants of LOCAL 716, but they nevertheless persisted in a pattern of distributing commonly abused and diverted opioids in geographic areas-and in such quantities, and with such frequency- that they knew or should have known these commonly abused controlled substances were not being prescribed and consumed for legitimate medical purposes.

193. If any of the Distributor Defendants adhered to effective controls to guard against diversion, LOCAL 716 would have avoided significant damages.

194. The Distributor Defendants made substantial profits over the years based on the diversion of opioids affecting LOCAL 716. Their participation and cooperation in a common enterprise has foreseeably caused damages to LOCAL 716. The Distributor Defendants knew full

well that LOCAL 716 would be unjustly forced to bear the costs of these injuries and damages.

195. The Distributor Defendants' intentional distribution of excessive amounts of prescription opioids to communities showed an intentional or reckless disregard for LOCAL 716. Their conduct poses a continuing economic threat to LOCAL 716.

196. The Manufacturer Defendants have engaged in similar wrongful conduct as alleged hereinabove as the Distributor Defendants.

National Retail Pharmacies Wrongful Conduct

197. Pharmacies must exercise reasonable care under the circumstances. This involves a duty not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative conduct, and thereafter realizes or should realize that such conduct has created an unreasonable risk of harm to another, is under a duty to exercise reasonable care to prevent the threatened harm.

198. Pharmacies are the "last line of defense" in keeping drugs from entering the illicit market. They are meant to be the drug experts in the healthcare delivery system and, as such, have considerable duties and responsibility in the oversight of patient care. Under the CSA and the Texas Prescription Monitoring Program ("TPMP"), pharmacies cannot blindly fill prescriptions written by a doctor if the prescription is not for a legitimate medical purpose. *See* Texas Admin. Code Section 315.3, *et seq.*; Article XLIII, *et seq.*

199. The CSA, the TRMP, Texas's Controlled Substances Act ("CSA"), and applicable state board of pharmacy regulations impose duties and requirements on the conduct of the National Retail Pharmacies Defendants. These requirements, along with their related regulations and agency interpretations, set a standard of care for pharmacy conduct.

200. The CSA, the TRMP, Texas's CSA, and applicable federal and state regulations require pharmacists to review each controlled substance prescription and, prior to dispensing medication, make a professional determination that the prescription is effective and valid.

201. Under the CSA, pharmacy registrants are required to "provide effective controls and procedures to guard against theft and diversion of controlled substances." 21 C.F.R. § 1301.71(a). In addition, 21 C.F.R. § 1306.04(a) states: "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription."

202. Pharmacists are required to ensure that prescriptions for controlled substances are valid and that they are issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice.

203. By filling prescriptions of questionable or suspicious origin in violation of the CSA, the TRMP, Texas's CSA, and applicable state board of pharmacy regulations, National Retail Pharmacies Defendants have violated federal statutory law and Texas common law, statutory law and other applicable state laws.

204. The DEA's 2010 "Practitioner's Manual" section on "Valid Prescription Requirements" instructs that "[a]n order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is an invalid prescription." Filling such a prescription is illegal. This Manual states: "The law does not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious origin. On the contrary, the pharmacist who deliberately ignores a questionable prescription when there is reason to believe it was not issued for a legitimate medical purpose may be prosecuted."

205. The DEA, as well as pharmacy boards, national industry associations, and continuing education programs, have provided extensive guidance to pharmacists concerning their duties to the public. The guidance teaches pharmacists how to identify red flags, which indicate to the pharmacist that there may be a problem with the legitimacy of a prescription presented by a patient. The guidance also tells pharmacists how to resolve the red flags and what to do if the red flags are unresolvable.

206. The industry guidance tells pharmacists how to recognize stolen prescription pads; prescription pads printed using a legitimate doctor's name, but with a different call back number that is answered by an accomplice of the drug-seeker; prescriptions written using fictitious patient names and addresses, and so on.

207. Questionable or suspicious prescriptions include: prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities) for controlled substances compared to other practitioners in the area; prescriptions which should last for a month in legitimate use, but are being refilled on a shorter basis; prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time; prescriptions that look "too good" or where the prescriber's handwriting is too legible; prescriptions with quantities or dosages that differ from usual medical usage; prescriptions that do not comply with standard abbreviations and/or contain no abbreviations; photocopied prescriptions; or prescriptions containing different handwritings. Most of the time, these attributes are not difficult to detect or recognize; they should be apparent to an adequately trained pharmacist.

208. Signs that a customer is seeking opioids for the purpose of diversion include customers who: appear to be returning too frequently; are seeking to fill a prescription written for a different person; appear at the pharmacy counter simultaneously, or within a short time, all

bearing similar prescriptions from the same physician; are not regular patrons or residents of the community, and show up with prescriptions from the same physician; drive long distances to have prescriptions filled; seek large volumes of controlled substances in the highest strength in each prescription; seek a combination of other drugs with opioids such as tranquilizers and muscle relaxers that can be used to create an "opioid cocktail"; and pay large amounts of cash for their prescriptions rather than using insurance. Ignoring these signs violates Texas common and statutory law.

209. Other "red flags" include when prescriptions that lack the technical requirements of a valid prescription, such as a verifiable DEA number and signature; prescriptions written in excess of the amount needed for proper therapeutic purposes; prescriptions obtained through disreputable or illegal web-based pharmacies; and patients receiving multiple types of narcotic pain killers on the same day.

210. All of these issues have been presented by the DEA in pharmacist training programs throughout the United States and have been used as examples by individual State Boards of Pharmacy and the National Association of Boards of Pharmacy.

211. Industry standards require pharmacists to contact the prescriber for verification or clarification whenever there is a question about any aspect of a prescription order. If a pharmacist is ever in doubt, he or she must ask for proper identification. If a pharmacist believes the prescription is forged or altered, he or she should not dispense it and call the local police. If a pharmacist believes he or she has discovered a pattern of prescription diversion, the local Board of Pharmacy must be contacted.

212. A standard of care for the National Retail Pharmacies Defendants is also set by applicable professional regulations in the State of Texas and other states in which they operate. It

is a violation of professional standards not to attempt to address the suspected addiction of a patient to a drug dispensed by the pharmacist, if there is reason to believe the patient may be addicted.

213. On information and belief, the National Retail Pharmacies Defendants regularly filled prescriptions in circumstances where red flags were present (and sometimes many red flags).

214. On information and belief, the National Retail Pharmacies Defendants regularly filled opioid prescriptions that would have been deemed questionable or suspicious by a reasonably prudent pharmacy.

215. On information and belief, the National Retail Pharmacies Defendants have not adequately trained or supervised their employees at the point of sale to investigate or report suspicious or invalid prescriptions, or protect against corruption or theft by employees or others.

216. On information and belief, the National Retail Pharmacies Defendants utilize monetary compensation programs for certain employees that are based, in part, on the number of prescriptions filled and dispensed. This type of compensation creates economic disincentives within the companies to change their practices. For example, there have been reports of chain store supervisory personnel directing pharmacists to fill prescriptions regardless of the red flags presented.

217. The National Retail Pharmacies Defendants have violated a voluntarily undertaken duty to the public. In news reports and other public documents, it has been reported that the National Retail Pharmacies Defendants, through their words or actions, have assured the public that issues affecting public health and safety are the highest priority for the defendants.

218. For example, in 2015, CVS publicly stated that "the abuse of controlled substance pain medication is a nationwide epidemic that is exacting a devastating toll upon individuals, families and communities. Pharmacists have a legal obligation under state to determine whether a

controlled substance was issued for a legitimate purpose and to decline to fill prescriptions they have reason to believe were issued for a non-legitimate purpose."

219. In failing to take adequate measures to prevent substantial opioid-related injuries that have affected Local 716, the National Retail Pharmacies Defendants have breached their duties under the "reasonable care" standard and their professional duties under the relevant standards of professional practice.

220. It is foreseeable to the National Retail Pharmacies Defendants that filling invalid or suspicious prescriptions for opioids would cause harm to individual pharmacy customers, Local 716 participants who may use the wrongfully-dispensed opioids, and Local 716 itself.

221. It is reasonably foreseeable to the National Retail Pharmacies Defendants that, when unintended users gain access to opioids, tragic yet preventable injuries and damages will result, including overdoses and death.

222. At all relevant times, the National Retail Pharmacies Defendants have engaged in improper dispensing practices, and continue to do so, despite knowing full well they could take measures to substantially eliminate their complicity in the opioid diversion.

223. At all relevant times, the National Retail Pharmacies Defendants engaged in these activities, and continue to do so, knowing full well that Local 716, in its role of providing medical care and services, would provide or pay for additional medical services, emergency services, and other necessary services, and would suffer the loss of substantial economic productivity.

224. It is reasonably foreseeable to the National Retail Pharmacies Defendants that Local 716 would be forced to bear substantial expenses as a result of the National Retail Pharmacies Defendants' acts.

225. The National Retail Pharmacies Defendants were on notice of their ongoing negligence or intentional misconduct in part because of their history of being penalized for violating their duties and legal requirements in other jurisdictions.

226. Defendants, CVS, Walgreens, and Wal-Mart each have one or more pharmacies that fill prescriptions for opioids that are operating within or in close proximity to the participants of Local 716.

227. Various State Boards of Pharmacy have also prosecuted and disciplined numerous pharmacists and pharmacy technicians employed by the National Retail Pharmacies Defendants for diversion of prescription opioids.

228. The National Retail Pharmacies Defendants were also aware of the magnitude of the opioid diversion crisis based on investigations into their practices elsewhere. For example, in 2013, Walgreens settled with the DEA for \$80 million, resolving allegations that it committed an unprecedented number of record-keeping and dispensing violations at various retail locations and a distribution center. As part of the settlement, Walgreens agreed to enhance its training and compliance programs, and to no longer compensate its pharmacists based on the volume of prescriptions filled

**COUNT I: RACKETEER INFLUENCED AND CORRUPT
ORGANIZATIONS ACT, 18 U.S.C. § 1961 et seq.**

229. Plaintiff reasserts the allegations in the foregoing paragraphs as if fully set out herein.

230. Defendants conducted and continue to conduct their business through illegitimate means in an association-in-fact enterprise and/or legal entity enterprise.

231. Defendants are persons under 18 U.S.C. § 1961(3) because they are entities holding a legal or beneficial interest in property.

232. Defendants have aggressively sought to increase and generate profits from the prescription opioid market by unlawfully increasing the volume of opioids manufactured, distributed, and sold.

233. As registrants under the CSA, Defendants are not permitted to limitlessly expand the opioid market through unlawful sales of regulated prescription opioids.

234. The CSA restricts and regulates Defendants' ability to manufacture and distribute prescription opioids, requiring Defendants to maintain effective preventative measures against opioid diversion, including, but not limited to: monitoring and identifying suspicious orders, preventing suspicious order from being filled, reporting suspicious orders to the DEA, and to not exceed sales quotas established by the DEA.

235. These precautionary methods created by the CSA were intentionally established to reduce or eliminate the potential for opioid diversion.

236. The Defendants found it impossible to maximize profits within the legal framework of the CSA. Choosing illegal profits over the law, Defendants systematically and fraudulently violated their statutory duties of maintaining effective anti-diversion measures through the intentional failure to report suspicious orders and the repeated unlawful sales of prescription opioids. As a result, Defendants illegally increased the annual production quotas for prescription opioids.

237. The term "enterprise" is defined as "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4). The definition of "enterprise" in § 1961(4) includes both legitimate and illegitimate enterprises. *Id.*

238. Manufacturer Defendants and Distributor Defendants forged an association-in-fact enterprise to perpetuate their illegal scheme of illegally increasing the production of prescription

opioids (collectively referred to as the “Opioid Diversion Enterprise”). In concert and through the Opioid Diversion Enterprise, Defendants participated in an illegal scheme, the purpose of which was to engage in the unlawful sale of prescription opioids while deceiving the public and regulators into believing that Defendants were faithfully complying with their statutory obligations. The Opioid Diversion Enterprise enabled Defendants to profit billions of dollars in the unlawful sale of opioids. As a direct result of Defendants’ fraudulent scheme, course of conduct, and pattern of racketeering activity, Defendants were able to extract billions of dollars in profit from millions of addicted Americans and Plaintiff’s members, while entities such as the Plaintiff experienced damages caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic.

239. Defendants formed an additional association-in-fact enterprise to unlawfully market the safety and efficacy of prescription opioids (collectively referred to as the “Opioids Promotion Enterprise”). The Opioids Promotion Enterprise is comprised of Defendants, including their employees and agents; Front Groups, including their employees and agents; and KOLs; as well as external and other as yet unknown marketing firms and distribution agents employed by Defendants in furtherance of the Opioids Promotion Enterprise. All entities are persons within the meaning of 18 U.S.C. § 1961(3) and acted to enable Defendants to fraudulently market opioids as scientifically proven as safe and effective.

240. The Opioids Promotion Enterprise is an organization that functioned as an ongoing organization and continuing unit. The Opioids Promotion Enterprise was created and organized to effectuate a pattern of racketeering activity and maintained systematic links for a common purpose: to ensure the continued prescription of opioids for chronic pain. Each of these entities, including the Defendants, is a “person” distinct from the Opioids Promotion Enterprise.

241. The Opioids Promotion Enterprise and Opioids Diversion Enterprise scheme empowered Defendants to make billions in unlawful sales of opioids and, in turn, increase and maintain high production quotas with the purpose of ensuring unlawfully increasing revenues, profits, and market share. As a direct result of the Defendants' fraudulent schemes, course of conduct, and pattern of racketeering activity, they were able to extract billions of dollars of revenue, while LOCAL 716 suffered injury caused by the reasonably foreseeable consequences of the opioid epidemic. LOCAL 716 is entitled to treble damages for its injuries under 18 U.S.C. § 1964(c).

242. Members of the Opioid Diversion Enterprise systematically and fraudulently violated their statutory duty to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders. As alleged herein, through the Defendants' scheme, members of the Opioid Diversion Enterprise repeatedly engaged in unlawful sales of painkillers, which in turn, artificially and illegally increased the annual production quotas for opioids allowed by the DEA. In doing so, the Defendants allowed hundreds of millions of pills to enter the illicit market, which allowed them to generate enormous profits.

243. Alternatively, Defendants were also members of a legal entity enterprise. The Healthcare Distribution Alliance ("HDA") is a distinct legal entity that qualifies as an enterprise under 18 U.S.C. § 1961(4). The HDA is a non-profit corporation formed under the laws of the District of Columbia and doing business in Virginia.

244. The Defendants utilized the HDA to conduct a RICO enterprise and to engage in the pattern of racketeering activity that gives rise to the RICO Count.

245. Each of the Defendants is a legal entity separate and distinct from the HDA. And,

the HDA serves the interests of distributors and manufacturers beyond the Defendants.

246. Therefore, the HDA exists separately from the Opioid Diversion Enterprise and the Opioid Promotion Enterprise, and each of the Defendants exists separately from the HDA. Therefore, the HDA itself serves as a RICO enterprise.

247. The association-in-fact enterprises (Opioid Promotion Enterprise and Opioid Diversion Enterprise) and the HDA were each used by the Defendants to engage in a pattern of racketeering activity. Therefore, the legal and association-in-fact enterprises are collectively referred to as the “RICO Enterprise.”

248. It is unlawful for a CSA registrant to manufacture a controlled substance in Schedule II, like prescription opioids, that is (1) not expressly authorized by its registration and by a quota assigned to it by DEA, or (2) in excess of a quota assigned to it by the DEA.

249. At all relevant times, the Defendants operated as an enterprise formed for the purpose of unlawfully increasing sales, revenues, and profits by disregarding their statutory duty to identify, investigate, halt, and report suspicious orders of opioids and diversion of their drugs into the illicit market, in order to unlawfully increase the quotas set by the DEA and allow them to collectively benefit from the unlawful formation of a greater pool of prescription opioids from which to profit. The Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

250. At all relevant times, the RICO Enterprise: (a) existed separately and distinctly from each Defendant; (b) was separate and distinct from the pattern of racketeering in which the Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the Defendants; (d) characterized by interpersonal relationships among the Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned

as a continuing unit. Each member of the RICO Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astonishing growth of profits supplied by fraudulently inflating opioid sales generated as a result of the RICO Enterprise's disregard for their duty to prevent diversion of their drugs into the illicit market and then requesting the DEA increase production quotas, all so that the Defendants would have a larger pool of prescription opioids from which to profit.

251. The RICO Enterprise also engaged in efforts to lobby against the DEA's authority to hold the Defendants liable for disregarding their duty to prevent diversion.

252. Members of the HDA lobbied for the passage of legislation to weaken the DEA's enforcement authority. The Ensuring Patient Access and Effective Drug Enforcement Act significantly reduced the DEA's ability to issue orders to show cause and to suspend and/or revoke registrations. The HDA contributed substantial amounts of money to political campaigns for federal candidates, state candidates, political action committees, and political parties.

253. The RICO Enterprise engaged in, and its activities affected, interstate and foreign commerce because the enterprise involved commercial activities across states lines, such as manufacture, sale, distribution, and shipment of prescription opioids throughout the United States and this jurisdiction, and the corresponding payment and/or receipt of money from the sale of the same.

254. The Defendants colluded to ensure that the quotas allowed by the DEA stayed high and ensured that suspicious orders were not reported to the DEA. By not reporting suspicious orders or diversion of prescription opioids, the Defendants ensured that the DEA had no basis for decreasing or refusing to increase the production quotas for prescription opioids due to diversion of suspicious orders. The Defendants influenced the DEA production quotas in the following ways:

- a. The Distributor Defendants assisted the enterprise and the Manufacturer Defendants in their lobbying efforts through the HDA;
- b. The Distributor Defendants invited the participation, oversight and control of the Manufacturer Defendants by including them in the HDA, including on the councils, committees, task forces, and working groups;
- c. The Distributor Defendants provided sales information to the Manufacturer Defendants regarding their prescription opioids, including reports of all opioids prescriptions filled by the Distributor Defendants;
- d. The Manufacturer Defendants used a chargeback program to ensure delivery of the Distributor Defendants' sales information;
- e. The Distributor Defendants accepted rebates and chargebacks for orders of prescription opioids;
- f. The Defendants identified suspicious orders of prescription opioids and then continued filling those unlawful orders, without reporting them, knowing that they were suspicious and/or being diverted into the illicit drug market;
- g. The Defendants refused to report suspicious orders of prescription opioids despite repeated investigation and punishment of the Distributor Defendants by the DEA for failure to report suspicious orders;
- h. The Defendants withheld information regarding suspicious orders and illicit diversion from the DEA because it would have revealed that the "medical need" for and the net disposal of their drugs did not justify the production quotas set by the DEA;

- i. The scheme devised and implemented by the Defendants amounted to a common course of conduct characterized by a refusal to maintain effective controls against diversion, and all designed and operated to ensure the continued unlawful sale of controlled substances.

255. Defendants took intentional and affirmative steps to conceal the RICO scheme through the use of unbranded advertisements, third parties, and the Front Groups to disguise the source of the Defendants' fraudulent statements.

256. Each time a participant in the illegal RICO scheme distributed a false statement by mail or wire, it committed a separate act of mail fraud or wire fraud under federal law, thereby demonstrating a pattern of racketeering activity.

257. Defendants used and caused to be used thousands of interstate mail and wire communications through uniform misrepresentations, concealments, and material omissions regarding the safety and efficacy of opioids and their compliance with the CSA's anti-diversion statutes. The Defendants committed this pattern of racketeering activity on a continual and regular basis with the intent to advance the illegal scheme of the Rico Enterprise.

258. Defendants also engaged in a pattern of racketeering activity in the unlawful manufacture, distribution, and sale of prescription opioids, a controlled substance under the CSA. Defendants routinely and intentionally furnished false, misleading, or incomplete information in their reports to the DEA and in their applications for production quotas.

259. LOCAL 716 has injuries that were directly caused by the Defendants' racketeering activities.

260. LOCAL 716 was most directly harmed and there are no other Plaintiffs better suited to seek a remedy for the economic harms at issue here.

261. The Plaintiff seeks all legal and equitable relief as allowed by law, including actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorney's fees and all costs and expenses of suit and pre- and post-judgment interest.

COUNT II: NEGLIGENCE PER SE

262. Plaintiff reasserts the allegations in the foregoing paragraphs as if fully set out herein.

263. Defendants have a duty to comply with the regulations of the Controlled Substances Act, 21 U.S.C. § 801 et seq.; Texas Prescription Monitoring Program ("TPMP"), Texas Admin. Code Section 315.3, *et seq.*; Texas's Controlled Substances Act ("CSA"), Tex. Code Annotated Section 481, *et seq.*; and regulations promulgated by both the federal government and the Texas State Board of Pharmacy governing the manufacture and distribution of controlled substances.

264. The CSA and Texas's CSA provide rules that Defendants must follow in maintaining their registration with the state board of pharmacy. Defendants, as registrants, are required to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels and comply with applicable state and local law. TEXAS CODE ANN. § 481.128 *et seq.*

265. Defendants' failure to comply with the CSA and the Texas CSA constitutes negligence per se. The failure to comply with comparable state statutes in Texas likewise constitutes negligence per se.

266. Complying with the CSA and Texas CSA and fulfilling Defendants' duties to prevent opioid diversion requires Defendants to know their customers, which includes, a mindfulness of the customer base, awareness of the average prescriptions filled per day, the percentage of controlled substances compared to overall purchases of drugs, a description of how

the dispenser fulfills its responsibility to ensure that prescriptions filled are for legitimate medical purposes, and identification of illegitimate pain centers that are the dispenser's most frequent prescribers of controlled substances such as opioids.

267. Defendants have failed to implement effective controls and procedures to prevent the diversion of opioids in violation of federal and Texas law.

268. Defendants have willfully ignored facts indicating the excessive distribution of enormous quantities of prescription opioids to retailers and dispensers who serve a customer base comprised of individuals who are abusing and/or dealing prescription opioids, resulting in an epidemic of addiction to prescription opioids.

269. Defendants, through their negligent acts and omissions, proximately caused the damages incurred by LOCAL 716 by negligently and/or recklessly disregarding the customs, standards, and practices within their industry as set forth by federal and Texas law

270. Defendants were negligent in failing to monitor and prevent the excessive distribution and diversion of prescription opioids.

271. LOCAL 716 has suffered and continues to suffer damages as the proximate result of Defendants' failures to comply with the CSA and Texas CSA.

272. LOCAL 716 is without fault and the injuries it has sustained would not have occurred in the ordinary course of events had the Defendants used due care commensurate to the dangers associated with the distribution of prescription opioids.

273. Defendants' violation of the CSA, Texas CSA, and applicable federal and state regulations constitutes negligence per se.

274. LOCAL 716 is within the class of persons the CSA, Texas CSA, and other applicable federal and state regulations are intended to protect.

275. The harm that has occurred is the type of harm that the CSA, Texas CSA, and other applicable federal and state regulations are intended to guard against.

COUNT III: NUISANCE

276. The Plaintiff reasserts the allegations of the foregoing paragraphs as if set forth fully herein.

277. The nuisance is the over-saturation of opioids to the participants of LOCAL 716 and in the geographic area served by LOCAL 716 for non-medical purposes, as well as the adverse social, economic, and human health outcomes associated with widespread illegal opioid use.

278. All Defendants substantially participated in nuisance-causing activities.

279. Defendants' nuisance-causing activities include the distribution of prescription opioids to the participants and their families of LOCAL 716, as well as to unintended users, including children, and people at risk of overdose or suicide, and criminals.

280. Defendants' nuisance-causing activities also include failing to implement effective controls and procedures in their supply chains to guard against theft, diversion and misuse of controlled substances, and their failure to adequately design and operate a system to detect, halt and report suspicious orders of controlled substances.

281. Defendants' activities unreasonably interfere with the economic rights of LOCAL 716.

282. The Defendants' interference with these rights of LOCAL 716 is unreasonable because it:

- a. Has harmed and will continue to harm the health services of and public peace of LOCAL 716;
- b. Has harmed and will continue to harm the participants which LOCAL 716 services;
- c. Is proscribed by statutes and regulation;

- d. Is of a continuing nature and it has produced long-lasting effects; and
- e. Defendants have reason to know their conduct has a significant, adverse effect upon LOCAL 716.

283. The nuisance undermines public health, quality of life, and safety. It has resulted in high rates of addiction, overdoses, dysfunction, and despair within participants and their families and entire communities.

284. The resources of funds such as LOCAL 716 are unreasonably consumed in efforts to address the prescription drug abuse epidemic, thereby eliminating available resources needed in other health care areas.

285. Defendants' nuisance-causing activities are not outweighed by the utility of Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever. There is no legitimately recognized societal interest in failing to identify, halt, and report suspicious opioid transactions.

286. At all times, all Defendants possessed the right and ability to control the nuisance-causing an outflow of opioids from points of sale and diversion. Manufacturer Defendants flooded the distribution channels and the geographic and demographic area of LOCAL 716 with opioid pills. Distributor Defendants had the power to shut off the supply of illicit opioids to participants and consumers in the geographic area served by LOCAL 716, yet did the opposite by flooding the U.S. with opioid pills.

287. As a direct and proximate result of the nuisance, LOCAL 716 has sustained economic harm by spending a substantial amount of money trying to remedy the harms caused by Defendants' nuisance-causing activity, including, but not limited to, payments made by the fund for opioid-related costs of medical care.

288. LOCAL 716 has also suffered unique harms different from individual opioid users and governmental entities at large, namely, that LOCAL 716 has been harmed in its proprietary and financial interests.

289. The effects of the nuisance can be abated, and the further occurrence of such harm and inconvenience can be prevented. All Defendants share in the responsibility for doing so.

290. Defendants should be required to pay the expenses LOCAL 716 has incurred or will incur in the future to fully abate the nuisance.

COUNT IV: NEGLIGENCE AND GROSS NEGLIGENCE

291. The Plaintiff reasserts the allegations of the foregoing paragraphs as if set forth fully herein.

292. Defendants owe a non-delegable duty to LOCAL 716 to conform their behavior to the legal standard of reasonable conduct under the circumstances, in the light of the apparent risks.

293. There is no social value to Defendants' challenged behavior. In fact, Defendants' entire conduct, behavior, actions, misrepresentations, conspiracies, and omissions are against the law.

294. On the other hand, there is an immense social value to the interests threatened by Defendants' behavior, namely the health, safety, and welfare of the participants of LOCAL 716.

295. Defendants' behavior caused a substantial injury and damage to LOCAL 716.

296. Defendants' conduct fell below the reasonable standard of care and was negligent.

Their negligent acts include:

- a. Consciously supplying the market in the geographic area served by LOCAL 716 with highly-addictive prescription opioids, including misrepresenting, understating, or obfuscating the highly addictive propensities of opioid pills;

- b. Using unsafe marketing, labeling, distribution, and dispensing practices, including failing to warn or advise physicians to conduct an addiction family history of each and every potential participant;
- c. Affirmatively enhancing the risk of harm from prescription opioids by failing to act as a last line of defense against diversion;
- d. Failing to properly train or investigate their employees;
- e. Failing to properly review and analyze prescription orders and data for red flags;
- f. Failing to report suspicious orders or refuse to fill them;
- g. Failing to provide effective controls and procedures to detect and/or guard against theft and diversion of controlled substances;
- h. Failing to police the integrity of their supply chains; and
- i. Creating misleading information with the intention of having prescribing physicians rely upon it.

297. Each Defendant had an ability to control the opioids at a time when it knew or should have known it was passing control of the opioids to an actor further down in the supply chain that was incompetent or acting illegally and should not be entrusted with the opioids.

298. Each Defendant sold prescription opioids in the supply chain knowing (a) there was a substantial likelihood many of the sales were for non-medical purposes and, (b) opioids are an inherently dangerous product when used for non-medical purposes, and (c) that every participant, before being prescribed even one opioid pill, needed to have a complete family history of addiction to alcohol and drugs, with any such history as a contraindication of any opioid use.

299. Defendants were negligent or reckless in not acquiring and utilizing special knowledge and special skills that relate to the dangerous activity in order to prevent or ameliorate such distinctive and significant dangers.

300. Controlled substances are dangerous commodities. Defendants breached their duty

to exercise the degree of care, prudence, watchfulness, and vigilance commensurate to the dangers involved in the transaction of their business.

301. Defendants were also negligent or reckless in failing to guard against foreseeable third-party misconduct, e.g., the foreseeable conduct of: corrupt employees, doctors, and/or criminals who buy and sell or otherwise acquire opioids for non-medical purposes, all of which has resulted in damages to LOCAL 716.

302. Defendants are in a limited class of registrants authorized to legally distribute controlled substances. This places Defendants in a position of great trust and responsibility vis-a-vis LOCAL 716 and its participant communities. Defendants owe a special duty to LOCAL 716. That duty cannot be delegated to another party.

303. LOCAL 716 is without fault, and the injuries to LOCAL 716 would not have happened in the ordinary course of events if the Defendants used due care commensurate to the dangers involved in the distribution and dispensing of controlled substances.

304. The aforementioned conduct of Defendants proximately caused damage to LOCAL 716.

COUNT V: UNJUST ENRICHMENT

305. Plaintiff reasserts the allegations in the foregoing paragraphs as if set forth fully herein.

306. LOCAL 716 has expended substantial amounts of money to address, remedy and/or mitigate addiction, illnesses, and medical conditions of its participants and their families caused by Defendants' conduct.

307. The expenditures by LOCAL 716 in providing healthcare services to its participants and their families who use opioids have added to Defendants' wealth. The expenditures by LOCAL

716 have helped sustain Defendants' businesses.

308. LOCAL 716 has conferred a benefit upon Defendants, by paying for what may be called Defendants' externalities - the costs of the harm caused by Defendants' negligent distribution and sales practices.

309. Defendants are aware of this obvious benefit, and that retention of this benefit is unjust.

310. Defendants made substantial profits while fueling the prescription drug epidemic in the geographic area served by LOCAL 716 and by LOCAL 716's payments for same.

311. Defendants continue to receive considerable profits from payments made by LOCAL 716.

312. Defendants have been unjustly enriched by their negligent, intentional, malicious, oppressive, illegal and unethical acts, omissions, and wrongdoing.

313. It would be inequitable to allow Defendants to retain the benefit or financial advantage of their wrongdoing.

314. LOCAL 716 demands judgment against each Defendant for restitution, disgorgement, and any other relief allowed in law or equity.

COUNT VI: COMMON LAW FRAUD

315. Plaintiff reasserts the allegations of the foregoing paragraphs as if set forth fully herein.

316. Manufacturer Defendants engaged in false representations and concealments of material facts regarding the use of opioids to treat chronic non-cancer pain.

317. Manufacturer Defendants made and/or disseminated deceptive statements, including, but not limited to, the following: (a) advertising that opioids improved long-term

functioning long-term and were suitable for the treatment of chronic non-cancer pain; (b) promoting the concept of pseudo-addiction; (c) brochures concerning indicators of possible opioid abuse; (d) suitability of opioids for high-risk patients; (e) publications presenting an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs; (f) concealment of funding of pro-opioid KOL doctors regarding treatment for chronic non-cancer pain; (g) downplaying of the risks of opioid addiction; (h) CMEs promoting the use of opioids to treat chronic non-cancer pain; (i) promotion of misleading scientific studies regarding the safety and efficacy of opioids for long-term treatment of chronic non-cancer pain; (j) misuse and promotion of data to mask the true safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including rates of abuse and addiction and the lack of validation for long-term efficacy; (k) misleading statements in education materials for Texas hospital doctors and staff under guise of educating them on new pain standards; (l) in-person detailing; and (m) withholding from Texas law enforcement the names of prescribers believed to be facilitating the diversion of its products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs.

318. Defendant Endo made and/or disseminated deceptive statements, including, but not limited to, the following: (a) false patient education materials; (b) advertising the ability of opioids to improve function long-term and the efficacy of opioids long-term for the treatment of chronic non-cancer pain; (c) promoting chronic opioid therapy as safe and effective for long term use for high- risk patients; (d) Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse; (e) concealing the true risk of addiction and promoting the misleading concept of pseudo-addiction; (f) promoting an unbalanced treatment of the long-term and dose-dependent

risks of opioids versus NSAIDs; (g) secretly funding pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain; (h) funding pro-opioid pain organizations responsible for egregious misrepresentations concerning the use of opioids to treat chronic non-cancer pain; (i) downplaying the risks of opioid addiction in the elderly; (j) CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain; (k) misleading scientific studies concluding opioids are safe and effective for the long-term treatment of chronic non-cancer pain and quality of life, while concealing contrary data; (l) funding and promoting pro-opioid KOLs concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudo-addiction; (m) manipulation of data regarding safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and (n) in-person detailing.

319. Defendant Janssen made and/or disseminated deceptive statements, including, but not limited to, the following: (a) patient education materials containing deceptive statements regarding the suitability, benefits, and efficacy of opioids; (b) stating that opioids were safe and effective for the long-term treatment of chronic non-cancer pain; (c) stating that opioids improve quality of life, while concealing contrary data; (d) concealing the true risk of addiction; (e) promoting the deceptive concept of pseudo-addiction; (f) promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious, and concealing this information; (g) presenting to the public and doctors an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs; (h) funding pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain; (i) funding pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer

pain; (j) using CMEs to promote false statements concerning the use of opioids to treat chronic non-cancer pain; and (k) in-person detailing.

320. Defendant Cephalon made and/or disseminated untrue, false, and deceptive statements minimizing the risk of addiction of opioids, promoting the concept of pseudo-addiction, advocating the use of opioids for chronic non-cancer pain, funding misleading CMEs, KOL doctors, and pain organizations, minimizing the addictiveness of Cephalon's potent rapid-onset opioids, and promoting the suitability of Cephalon's rapid-onset opioids to general practitioners, neurologists, sports medicine specialists, and workers' compensation programs.

321. Defendant Actavis made and/or disseminated deceptive statements, including, but not limited to, the following: (a) promotion of use of opioids to treat chronic non-cancer pain to Texas prescribers through in-person detailing; (b) advertising that opioids were safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improved quality of life; and (c) advertising that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain.

322. These false representations and concealments were reasonably calculated to deceive prescribing physicians in the geographic areas served by LOCAL 716, were made with the intent to deceive, and did, in fact, deceive physicians who prescribed opioids for chronic pain.

323. But for these false representations and concealments of material fact, LOCAL 716 would not have incurred substantial costs and economic loss.

324. As a direct and proximate cause of the Manufacturer Defendants' fraudulent conduct, LOCAL 716 has suffered damages.

COUNT VII: CIVIL CONSPIRACY

325. Plaintiff reasserts the allegations in the foregoing paragraphs as if fully set out

herein.

326. The Manufacturer Defendants continuously supplied prescription opioids to the Distributor Defendants despite having actual or constructive knowledge that said Distributors were habitually breaching their common law duties and violating the CSA. The Distributor Defendants continuously flooded prescription opioids in the pertinent geographic areas despite having actual or constructive knowledge that said opioid pills were being overprescribed, illegally diverted, and/or otherwise abused, all in violation of the CSA.

327. No Defendant in this opioid network would have succeeded in profiting so significantly from the opioid epidemic without the concerted conduct of the other party, and none would have succeeded so significantly without engaging in the wrongful conduct as herein alleged.

328. The Manufacturer Defendants likewise benefitted from this distribution conspiracy in that the more pervasive opioid diversion became, the more the Manufacturer Defendants profited. Despite access to the same information in the hands of the Distributor Defendants, the Manufacturer Defendants ignored the warning signs of opioid diversion.

329. As a result of the concerted actions between and among the Defendants, LOCAL 716 has suffered damages.

330. LOCAL 716 demands judgment against each Defendant for compensatory damages.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff LOCAL 716 demands trial by jury on all counts so triable and prays that the Court grant the following relief:

- a. injunctive Relief;
- b. compensatory, consequential, and incidental damages;

- c. restitution;
- d. punitive damages;
- e. attorneys' fees and costs; and
- f. all such other relief this Court deems just and fair.

Dated, this the 7th day of April 2020.

Respectfully submitted,

IBEW LOCAL 716 ELECTRICAL MEDICAL TRUST

By Its Attorneys,

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